

**AMENDMENT ENTRY**

Amendment of 11/17/09 has been entered. Claims 1 and 3-10 are pending.  
Claims 1 and 3-10 are under consideration.

The elected species remain as those stated in the action of 8/17/10.

**OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN**

The amendment has overcome previously stated issues as follows:

The objection to the drawings.

The rejection of claim(s) 1-19 and 21-23 under 35 USC 112, 2<sup>nd</sup> paragraph.  
Claim 1 has been amended so extensively that any 112, 2<sup>nd</sup> considerations of it and its dependents will be considered anew. Claim 12 and its dependents have been cancelled

The rejection of claim(s) 8 and 18 under 35 USC 112, 1st paragraph, since both these claims have been cancelled.

The prior art rejection of claim(s) 1-5, 11-12, 15 and 23 based upon Hamaway et al. The rejection has been withdrawn because the embodiment in which one exposes test lymphocytes to a "cytokine which can inhibit mononuclear cell activation and proliferation" is no longer encompassed by claim 1 and its dependents. Claim 12 and its dependents have been cancelled.

The prior art rejection of claim(s) 12, 14, 16-17 and 22 based upon Stafford et al, since these claims have been cancelled.

The prior art rejection of claim(s) 12-13, 18-19 and 21 based upon Karpas et al, since these claims have been cancelled.

### **NEW REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites plural "agents" and "medicaments", while base claim 6 recites a singular "agent" and a singular "medicament".

### **NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH**

Claims 1 and 3-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites new matter.

Specifically, claim 1 fails to recite anything about providing the target antigen and the neutralizing antibodies in a medium for cell culture. Since the claim does not specify what the target antigen, the neutralizing antibodies, and the test lymphocytes are placed in, the claim is broader in scope than that set forth in the original disclosure. For example, the open/unspecified scope of the claim permits the target antigen, neutralizing antibodies, and lymphocytes to be provided in some kind of "medium" (e.g. PBS?) which would be suitable for cell viability, but not for cell culture.

### **ART OF INTEREST**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frentsch et al (7,659,084, cited on PTO-892) is noted for teaching methods of detecting antigen-specific T-cells.

### **FINALITY**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## **CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax number where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 4/8/10 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644